IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,)
Plaintiff,)
V.) C.A. No. 21-258 (CFC)
BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC))
NEUROMODULATION CORP.,)
Defendants.)
)

NEVRO CORP.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE BSC'S INEQUITABLE CONDUCT AND UNCLEAN HANDS **AFFIRMATIVE DEFENSES**

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I. INTRODUCTION

BSC's Answering Brief (D.I. 33) relies on irrelevant diversions, mischaracterizations of its own pleading, and incorrect statements of law, but none of BSC's arguments compensates for BSC's failure to meet basic pleading requirements for both inequitable conduct and unclean hands. A straightforward application of the law to BSC's pleading yields only one reasonable conclusion: BSC's defenses should be dismissed, and the parties and Court should be spared further time-consuming litigation on these issues.¹

II. ARGUMENT

A. BSC's Inequitable Conduct Defense Should Be Stricken

1. BSC Fails to Adequately Plead Materiality

BSC fails to plead materiality and non-cumulativeness under *Exergen* for three separate reasons.

First, as Nevro explained (D.I. 32 at 7-9), *Exergen* requires identifying "particular claim limitations, or [a] combination of claim limitations, that are supposedly absent from the information of record." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329-30 (Fed. Cir. 2009). BSC's pleading, however, *never identifies any such claim limitations. See* D.I. 27 at 15-18. Tellingly, in its

Contrary to BSC's assertion, Nevro dismissed its California lawsuit only after BSC agreed not to release high-frequency paresthesia-free products. *See* Ex. A; D.I. 34, Ex. A.

Answering Brief, BSC merely asserts that "Nevro is well aware" of what the missing limitations are, without identifying them. D.I. 33 at 11. Rule 9(b) and Exergen do not allow parties to avoid fundamental pleading requirements by resorting to obtuse statements about the other party's supposed knowledge. BSC's inequitable conduct defense should be dismissed for this reason alone. See Exergen, 575 F.3d at 1329-30; Analog Devices, Inc. v. Xilinx, Inc., C.A. No. 19-2225-RGA, 2021 WL 466859, at *2-3 (D. Del. Feb. 9, 2021) (materiality not sufficiently pled where contents of prior art before PTO were not addressed).²

Second, BSC's inequitable conduct defense fails because it does not "establish[]...a prima facie case of unpatentability of a claim." *Exergen*, 575 F.3d at 1330 (quoting 37 C.F.R § 1.56(b)(1)); *see Telebrands Corp. v. IbyOne Prod., Inc.*, C.A. No. 17-997-JFB-SRF, 2018 WL 3696558, at *3 (D. Del. Aug. 3, 2018) ³; D.I. 32 at 7-9. BSC's conclusory assertion that Yearwood "is an anticipatory reference" does not satisfy *Exergen*'s specificity requirement. D.I. 33 at 10-11. BSC itself recently explained why in another case, informing this Court that accepting such an argument would "make a mockery" of *Exergen*:

BSC also inconsistently contends that "the prior art of record rendered all of Nevro's claims unpatentable." D.I. 33 at 11 n.6.

As Nevro explained (D.I. 32 at 7-8) and contrary to BSC's claim (D.I. 33 at 10 n.5), in failing to allege "how" Yearwood anticipates, BSC also fails to identify "what" specific claim limitations Yearwood discloses.

Defendants assert that they need not identify particular claim limitations as *Exergen* requires, because they include a blanket allegation that the Olympus devices embody the claimed inventions, such that they "necessarily identify" the relevant limitations—"i.e. all of them."... Accepting Defendants' assertion as sufficient would make a mockery of both the specificity required by Exergen and the Federal Circuit's effort in Therasense to end the plague of [inequitable conduct allegations].

Bos. Sci. Corp. v. Micro-Tech Endoscopy USA Inc., C.A. No. 18-1869-CFC-CJB, D.I. 102 (Ex. B at 2) (emphasis added); see also id., D.I. 96 (Ex. C at 2). The Court accepted BSC's argument there and struck the defense. See Micro-Tech, 2020 WL 1550781, at *2. BSC's about-face now lacks both legal support and credibility.

BSC's heavy reliance on plainly inadmissible "expert discovery in the California Action" only underscores that BSC's pleading is defective. D.I. 33 at 11; see Cephalon, Inc. v. Slayback Pharma Ltd. Liab. Co., C.A. No. 17-1154-CFC, 2019 WL 3497105, at *1 (D. Del. Aug. 1, 2019); Analog Devices, 2021 WL 466859, at *2 n.3.⁴

Third, BSC fails to allege any rationale to combine any references with Yearwood. While BSC contends that disclosing general obviousness combinations "is more than sufficient" (D.I. 33 at 8), its cited case shows the opposite. In *Diebold*, the pleadings detailed "numerous reasons and motivations that would lead a person

BSC dropped its inequitable conduct theory in the California case by omitting it from expert reports. *See* D.I. 34, Ex. E at 28; Ex. D at Tr. 241:5-13.

having ordinary skill in the art to the alleged inventions of the [asserted] patent." *Diebold Nixdorf, Inc. v. Hyosung Tns, Inc.*, C.A. No. 19-1695-LPS, 2021 WL 861734, at *4 (D. Del. Mar. 4, 2021). BSC's mere listing of obviousness combinations here is a far cry from such a robust pleading.

Accordingly, BSC's inequitable conduct defense should be stricken for failure to meet basic *Exergen* pleading requirements.

2. BSC Fails to Adequately Plead Intent

As Nevro explained (D.I. 32 at 10-14), BSC failed to adequately plead intent to deceive.

In response, BSC first argues that "Mr. Thacker's direct access to and incorporation of this work into the Alataris Patents, coupled with his subsequent withholding of it from the Patent Office supports a plausible inference of specific intent." D.I. 33 at 12-13. This argument fails because BSC *at most* alleges that Mr. Thacker knew of the Yearwood references and did not disclose them to the PTO. It is well-established that "[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive." *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs. Inc.*, C.A. No. 17-275-LPS, C.A. No. 17-353-LPS, 2019 WL 668843, at *2 (D. Del. Feb. 19, 2019). That is exactly the case here.

The only case BSC cites to support this argument—*Illumina Inc. v. BGI Genomics Co.*, No. 20-CV-01465-WHO, 2021 WL 428632, at *1-4 (N.D. Cal. Feb. 8, 2021)—in fact shows why BSC's allegations fail. There, the defendant alleged the inventors copied "two specific methodologies that were key to creating the claimed nucleotides," based on notations in an inventor's laboratory notebook. *Id.* The court found such allegations barely sufficient to allege intent. *Id.* at *4 ("It is a closer question..."). Here, in contrast, BSC's Answer alleges *no facts* showing that Mr. Thacker copied or "incorporat[ed]" anything from Yearwood into the Alataris patents. Thus, BSC's bare allegation that Mr. Thacker knew of Yearwood and did not disclose it fails.

BSC next contends it need not present direct evidence of intent at the pleading stage. D.I. 33 at 13. BSC urges that "pleadings establishing knowledge of withheld material information" can also "lead to an inference of specific intent to deceive the PTO," and asserts Nevro does not dispute that. *Id.* BSC's argument, however, runs directly contrary to *Exergen*, which makes clear that mere knowledge of withheld material information does *not* suffice to prove intent. *See* 575 F.3d at 1331; *see also Illumina*, 2021 WL 428632, at *4 (emphasizing that defendant "has not simply alleged that [the inventors] were aware of [the prior art] and failed to

disclose it").⁵ Additionally, Nevro *has* disputed that Mr. Thacker had knowledge of material information at the time he allegedly withheld the Yearwood documents. *See* D.I. 32 at 11. BSC ignores the fact that the Alataris patents were filed three years after Mr. Thacker allegedly was exposed to Yearwood, and pleads no facts regarding Mr. Thacker's state of mind at the relevant time. BSC therefore does not even have circumstantial support for its claims of intent.

Next, BSC makes excuses for the fact that, despite having already taken full discovery on inequitable conduct, it is unable to plead even a single pertinent fact and instead relies on a conclusory half-sentence based purely "on information and belief." D.I. 33 at 13-14; D.I. 27 at 18. However, "[p]leading on 'information and belief' is permitted under Rule 9(b) when essential information lies uniquely within another party's control...." *Exergen*, 575 F.3d at 1330. BSC cannot satisfy that requirement, as BSC has not only had the opportunity to ask Mr. Thacker about the Yearwood studies during multiple rounds of discovery, but in fact did so in Mr. Thacker's two-day deposition in December 2017. Thus, BSC cannot excuse its bare-bones pleading by intoning on "information and belief."

BSC's *Zadro* case likewise confirms that "an intent to deceive cannot be inferred solely based upon the failure to disclose known information, even if it is highly material." 2019 WL 1100470, at *4-5.

Finally, BSC's assertion that it has "provided multiple and specific factual allegations regarding Mr. Thacker's intent to deceive" fails. D.I. 33 at 15. Each such allegation (*e.g.*, that Mr. Thacker "received and reviewed" the Yearwood References), relates at most to Mr. Thacker's knowledge of the references, not to his intent. Again, mere knowledge of references is insufficient to plead intent. *See Exergen*, 575 F.3d at 1331; *Pac. Bio.*, 2019 WL 668843 at *2; *Illumina*, 2021 WL 428632 at *4.

Consequently, BSC's inequitable conduct defense should be stricken for failure to adequately plead knowledge of materiality and intent to deceive.

B. BSC's Unclean Hands Defense Should Be Stricken

As Nevro explained (D.I. 32 at 15-18), BSC's conclusory unclean hands defense fails to satisfy fundamental pleading requirements, and courts have definitively rejected similar allegations as "bogus."

In response, BSC first incorrectly argues that Rule 9(b) does not apply. D.I. 33 at 15-16. This district has held that "unclean hands must be plead with particularity under Rule 9(b)." *Bench Walk Lighting LLC v. Everlight Elecs. Co.*, C.A. No. 20-49-RGA, 2020 WL 5128086, at *1 (D. Del. Aug. 31, 2020). At a minimum, Rule 9(b) applies to "unclean hands that sounds in fraud." *Cephalon*, 2019 WL 3497105, at *1. That is the case here. BSC asserts that it "has not accused Nevro of fraud," D.I. 33 at 16, but in fact it has. Namely, BSC accuses Nevro of "at

least bad faith and deceit." *Id.* "Deceit" and "fraud" are synonyms. *See* https://www.merriam-webster.com/dictionary/fraud (defining fraud as "deceit" or "an act of deceiving or misrepresenting"). BSC cannot evade Rule 9(b) by substituting "deceit" for "fraud." Additionally, in its Third Amended Complaint in C.A. No. 16-1163, which BSC relies on to support its unclean hands defense, BSC accuses Nevro of "malicious, *fraudulent*, deliberate and willful" conduct. *See* Ex. E, ¶ 248 (emphasis added); D.I. 33 at 6, 19.6 Thus, Rule 9(b) applies based on BSC's own pleadings and arguments, and BSC's conclusory defense should be stricken for failure to plead with particularity.

BSC also fails to meet the substantive requirements for pleading unclean hands—regardless of whether Rule 9(b) or Rule 8 applies. Under both standards, BSC must plead sufficient facts to establish the elements of unclean hands. *See Ashcroft v. Iqbal*, 556 US 662, 678 (2009). BSC has not done so.

First, BSC's allegation that "Nevro is an adjudicated willful infringer...[and] intend[s] to continue infringing" does not constitute unconscionable, morally-shocking conduct—a key requirement of unclean hands. D.I. 27 at 14; D.I. 32 at 15-17; *see Magnesystems, Inc. v. Nikken, Inc.*, 933 F. Supp. 944, 953 (C.D. Cal. 1996) (rejecting unclean hands defense based on willful patent

BSC's reliance on exhibits outside its Answer is improper. *See Cephalon*, 2019 WL 3497105, at *1.

infringement). BSC fails to address this requirement in its Answering Brief, and thus concedes its defense is deficient. BSC also fails to distinguish *Magnesystems*—which describes an allegation nearly identical to BSC's as "bogus" and an "unprecedented stretch of the [unclean hands] doctrine." 933 F. Supp. at 953. BSC's purported distinctions about procedural posture and post-verdict infringement make no difference to *Magnesystem*'s sound rationale, and BSC's conclusory assertion about copying is also defective as explained next. D.I. 33 at 17-18.

Second, BSC's allegation that "Nevro's SCS platform was developed using Boston Scientific confidential information and patented technology" lacks any nexus to Nevro's patent infringement claims, much less a "close" nexus. D.I. 27 at 14; D.I. 32 at 17-18. Recognizing this fatal deficiency, in its Answering Brief, BSC tries to rewrite and expand upon its single-sentence allegation. BSC contends that Nevro used unspecified BSC "documents and information to develop the Asserted Patents," and that BSC's "lead technology...was part of the work described in Nevro's Asserted Patents." D.I. 33 at 16-19. These vague assertions cannot save BSC's deficient pleading for several reasons.

To start, BSC's *pleading* does not contain any such allegations, much less supporting facts. BSC's pleading merely alleges that "Nevro's SCS platform"—

not Nevro's asserted patents—was developed using BSC information. D.I. 27 at 14.

Furthermore, even if BSC's allegation were directed to Nevro's asserted patents,

such a bare, unsupported statement that Nevro obtained its patents by copying unidentified BSC "information" is exactly the sort of unclean hands allegation that requires specificity. It is telling that BSC has had access to reams of Nevro documents for years, yet cannot muster even a single sentence with a single specific fact linking BSC's alleged trade secrets to Nevro's asserted patents.

BSC's attempt to link its "lead technology" to Nevro's asserted patents also makes no sense. Nevro's asserted paresthesia-free patents have nothing to do with BSC's patents on including monofilaments or epoxy in particular portions of a lead, much less have the "close" nexus required to plead unclean hands. Under BSC's reasoning, infringement of a patent directed to any aspect of an SCS system by Nevro would permit holding all of Nevro's patents unenforceable due to unclean hands. That is not the law. See Highmark, Inc. v. UPMC Health Plan, Inc., 276 F.3d 160, 174 (3d Cir. 2001); *Magnesystems*, 933 F. Supp. at 953. BSC's circumlocutions about leads being "part of the work described" in Nevro's patents cannot cure that glaring defect. Nevro's patents claim innovative therapy techniques and are agnostic about the substances used in manufacturing the leads. BSC's argument that SCS therapy is not possible without leads, D.I. 33 at 20, is even further afield. By that logic, infringing a patent on a screw or electricity would establish a close nexus to Nevro's patents, which is unsupportable.

This case bears no resemblance to BSC's cited cases. In those cases, the "unclean" conduct bore an immediate and necessary relationship to the claims asserted in the case, such as where a competitor stole trade secrets, patented those same trade secrets, and sued its competitor on that patent. *See, e.g., Gilead Scis., Inc. v. Merck & Co, Inc.*, No. 13-CV-04057-BLF, 2016 WL 3143943, at *26-29, 32 (N.D. Cal. June 6, 2016). Here, in contrast, BSC has not pled any facts showing that Nevro's alleged patent infringement or trade secret misappropriation has anything to do with Nevro's asserted patents, beyond the generalized notion that all the information somehow relates to "Nevro's SCS platform." Thus, BSC's attempt to import its patent and trade secret claims into this case under the guise of an unclean hands defense should be rejected.

Lastly, BSC does not dispute that its reference to inequitable conduct within its unclean hands defense merely rehashes BSC's inequitable conduct defense, and therefore should be stricken as redundant. *See* D.I. 32 at 18.

BSC's conclusory and unsupported defense should be stricken now to save the parties and the Court the burden of litigating a defense that fails at the outset.

III. CONCLUSION

For these reasons, Nevro's motion should be granted.

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CERTIFICATE OF COMPLIANCE

The undersigned counsel hereby certifies that the foregoing document contains 2,498 words, which were counted by using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count includes only the body of the brief. The word count does not include the cover page, tables of contents and authorities, or the counsel blocks.

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CERTIFICATE OF SERVICE

I hereby certify that on March 1, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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